

WE CLAIM:

- 1 1. A taste masking coating composition comprising:
2 a copolymer of acrylate and methacrylate with a quaternary ammonium group in
3 combination with sodium carboxymethylcellulose; and
4 a polyvinyl alcohol-polyethylene glycol copolymer.
- 1 2. The taste masking coating composition of claim 1, wherein a ratio of the
2 copolymer of acrylate and methacrylate to the copolymer of polyvinyl alcohol-
3 polyethylene glycol is about 1:2 to 1:3.
- 1 3. The taste masking coating composition of claim 1, wherein the concentration
2 of the copolymer of acrylate and methacrylate is about 20% w/w to about 30% w/w of the
3 taste masking coating composition.
- 1 4. The taste masking coating composition of claim 1, wherein the concentration
2 of the copolymer of polyvinyl alcohol-polyethylene glycol is about 65% w/w to about
3 75% w/w of the total coating composition.
- 1 5. The taste masking coating composition of claim 1, further comprising a
2 lubricant.
- 1 6. The taste masking coating composition of claim 3, wherein the lubricant
2 comprises one or more of talc, glyceryl monostearate, magnesium stearate, and colloidal
3 silica.
- 1 7. The taste masking coating composition of claim 5, wherein the lubricant
2 comprises up to 10% of the dry weight of the taste masking coating composition.
- 1 8. The taste masking coating composition of claim 1, wherein the taste masking
2 coating composition is coated on one or more of a core, granule, pellet, active
3 pharmaceutical ingredient, or dosage form, wherein the core, granule, pellet, or dosage
4 form contains an active pharmaceutical ingredient.
- 1 9. The taste masking coating composition of claim 8, wherein more than 60% of
2 the active pharmaceutical ingredient released in 15 minutes, more than 80% of the active
3 pharmaceutical ingredient is released in 30 minutes, and more than 90% of the active
4 pharmaceutical ingredient is released in 45 minutes when the core, granule, pellet, or
5 dosage form is placed in 900 ml of a glycine buffer (pH 3.0) with apparatus 2 with stirring

6 at 75 RPM and aliquots of the solution are analyzed spectrophotometrically at a
7 wavelength of 259 nm.

1 10. An immediate release, taste-masked pharmaceutical composition for oral
2 administration, the pharmaceutical composition comprising

3 a core;

4 an active pharmaceutical ingredient, wherein the core includes the active
5 pharmaceutical ingredient; and

6 a taste masking coating, the taste masking coating comprising a combination of (i)
7 copolymers of acrylate and methacrylate with a quaternary ammonium group in
8 combination with sodium carboxymethylcellulose and (ii) polyvinyl alcohol-polyethylene
9 glycol copolymer,

10 wherein the core and the active pharmaceutical ingredient are coated with the taste
11 masking coating.

1 11. The pharmaceutical composition of claim 10, wherein more than 60% of the
2 active pharmaceutical ingredient is released in about 15 minutes, more than 80% of the
3 active pharmaceutical ingredient is released in about 30 minutes, and more than 90% of
4 the active pharmaceutical ingredient is released in about 45 minutes when the
5 pharmaceutical composition is placed in 900 ml of a glycine buffer (pH 3.0) with
6 apparatus 2 with stirring at 75 RPM and aliquots of the solution are analyzed
7 spectrophotometrically at a wavelength of 259 nm.

1 12. The pharmaceutical composition of claim 10, wherein the ratio of (i) and (ii) is
2 about 1:2 to about 1:3.

1 13. The pharmaceutical composition of claim 10, wherein the concentration of (i)
2 is between about 20% w/w and about 30% w/w of the taste masking coating.

1 14. The pharmaceutical composition of claim 10, wherein the concentration of (ii)
2 is between about 65% w/w and about 75% w/w of the total coating composition.

1 15. The pharmaceutical composition of claim 10, wherein the taste masking
2 coating further comprises one or more lubricants.

1 16. The pharmaceutical composition of claim 15, wherein the lubricant comprises
2 one or more of talc, glyceryl monostearate, magnesium stearate, and colloidal silica.

1 17. The pharmaceutical composition of claim 15, wherein the lubricant comprises
2 up to 10% of the dry weight of the taste masking coating composition.

1 18. The pharmaceutical composition of claim 10, wherein the taste masking
2 coating comprises between about 10% w/w and about 40% w/w of the core and active
3 pharmaceutical ingredient.

1 19. The pharmaceutical composition of claim 10, wherein the coating comprises
2 between about 10% w/w and about 25% w/w of the core and active pharmaceutical
3 ingredient.

1 20. The pharmaceutical composition of claim 10, wherein the core comprises one
2 or more of an insoluble material, a soluble material, and a swellable material.

1 21. The pharmaceutical composition of claim 20, wherein the core comprises an
2 insoluble material.

1 22. The pharmaceutical composition of claim 21, wherein the insoluble material
2 comprises one or more of sand, glass, microcrystalline cellulose, and plastic.

1 23. The pharmaceutical composition of claim 20, wherein the core comprises a
2 soluble material.

1 24. The pharmaceutical composition of claim 23, wherein the soluble material
2 comprises one or more sugars comprising glucose, mannitol, lactose, xylitol, dextrose,
3 sucrose, and mixtures thereof.

1 25. The pharmaceutical composition of claim 20, wherein the core comprises a
2 swellable material.

1 26. The pharmaceutical composition of claim 25, wherein the swellable material
2 comprises hydroxypropyl methylcellulose.

1 27. The pharmaceutical composition of claim 10, wherein the active
2 pharmaceutical ingredient comprises one or more of alkaloids, antacids, analgesics,
3 anabolic agents, anti-anginal drugs, anti-allergy agents, anti-arrhythmia agents,
4 antiasthmatics, antibiotics, anticholesterolemics, anticonvulsants, anticoagulants,
5 antidepressants, antidiarrheal preparations, anti-emetics, antihistamines, antihypertensives,
6 anti-infectives, anti-inflammatories, antilipid agents, antimanics, anti-migraine agents,
7 antinauseants, antipsychotics, antistroke agents, antithyroid preparations, anabolic drugs,
8 antiobesity agents, antiparasitics, antipsychotics, antipyretics, antispasmodics,

9 antithrombotics, antitumor agents, antitussives, antiulcer agents, anti-uricemic agents,
10 anxiolytic agents, appetite stimulants, appetite suppressants, beta-blocking agents,
11 bronchodilators, cardiovascular agents, cerebral dilators, chelating agents, cholecystekinin
12 antagonists, chemotherapeutic agents, cholesterol reducing agents, cognition activators,
13 contraceptives, coronary dilators, cough suppressants, CNS drugs, decongestants, diabetes
14 agents, diuretics, emollients, enzymes, erythropoietic drugs, expectorants, fertility agents,
15 fungicides, gastrointestinal agents, growth regulators, hormone replacement agents,
16 hyperglycemic agents, hypoglycemic agents, ion-exchange resins, laxatives, migraine
17 treatments, mineral supplements, mucolytics, narcotics, neuroleptics, neuromuscular
18 drugs, non-steroidal anti-inflammatories (NSAIDs), nutritional additives, peripheral
19 vasodilators, polypeptides, prostaglandins, psychotropics, renin inhibitors, respiratory
20 stimulants, sedatives, steroids, stimulants, sympatholytics, thyroid preparations,
21 tranquilizers, uterine relaxants, vaginal preparations, vasoconstrictors, vasodilators,
22 vertigo agents, vitamins, and wound healing agents.

1 28. The pharmaceutical composition of claim 27, wherein the analgesic comprises
2 one or more of acetaminophen, aspirin, ibuprofen, naproxen, and ketoprofen.

1 29. The pharmaceutical composition of claim 27, wherein the antibiotic comprise
2 one or more of cefuroxime axetil, cefpodoxime proxetil, ciprofloxacin, erythromycin, and
3 clarithromycin.

1 30. The pharmaceutical composition of claim 27, wherein the antibiotic comprises
2 cefpodoxime proxetil.

1 31. The pharmaceutical composition of claim 27, wherein the gastrointestinal agent
2 comprises one or more of loperamide, famotidine, ranitidine, and cimetidine.

1 32. The pharmaceutical composition of claim 27, wherein the cardiovascular
2 agents comprise one or more of irbesartan, captopril, and lisinopril.

1 33. The pharmaceutical composition of claim 27, wherein the CNS drug comprises
2 nefazodone and buspirone.

1 34. The pharmaceutical composition of claim 27, wherein the antihistamine
2 comprises chlorpheniramine and astemizole.

1 35. The pharmaceutical composition of claim 27, wherein the cholesterol reducing
2 agent comprises a statin.

1 36. The pharmaceutical composition of claim 10, wherein the taste-masked
2 pharmaceutical composition comprises one or more of sprinkles, dry powder, suspension,
3 emulsion, whole chewable tablets, and dispersible tablets.

1 37. The pharmaceutical composition of claim 10, wherein the taste-masking
2 coating is applied to the active pharmaceutical ingredient.

1 38. The pharmaceutical composition of claim 10, wherein the taste masking
2 coating further comprises one or more of plasticizers, coloring agents, and gloss
3 producers.

1 39. A process for preparing a taste masking coating composition, the process
2 comprising combining (i) a copolymer of acrylate and methacrylate with a quaternary
3 ammonium group in combination with sodium carboxymethylcellulose and (ii) a polyvinyl
4 alcohol-polyethylene glycol copolymer.

1 40. The process of claim 39, further comprising adding one or more of a lubricant,
2 a plasticizer, a coloring agent, and a gloss producer.

1 41. A process for preparing an immediate release taste-masked pharmaceutical
2 composition for oral administration, the process comprising:

3 coating a core containing an active pharmaceutical ingredient with a taste
4 masking coating composition, the taste masking coating composition comprising a
5 combination of (i) copolymers of acrylate and methacrylate with a quaternary ammonium
6 group in combination with sodium carboxymethylcellulose and (ii) a polyvinyl alcohol-
7 polyethylene glycol copolymer.

1 42. The process of claim 41, wherein the ratio of (i) to (ii) is between about 1:2 and
2 about 1:3.

1 43. The process of claim 41, wherein the concentration of (i) is between about 20%
2 w/w and about 30% w/w of the total coating composition.

1 44. The process of claim 41, wherein the concentration of (ii) is between about
2 65% w/w and about 75% w/w of the total coating composition.

1 45. The process of claim 41, wherein the taste masking coating composition further
2 comprises one or more lubricants.

1 46. The process of claim 45, wherein the lubricant comprises one or more of talc,
2 glyceryl monostearate, magnesium stearate, and colloidal silica.

1 47. The process of claim 45, wherein the lubricant comprises up to about 10% of
2 the dry weight of the taste masking coating composition.

1 48. The process of claim 41, wherein the coating comprises between about 10%
2 w/w and about 40% w/w of the active pharmaceutical ingredient-containing core.

1 49. The process of claim 41, wherein the coating comprises between about 10%
2 w/w and about 25% w/w of the active pharmaceutical ingredient-containing core.

1 50. The process of claim 41, wherein the core comprises one or more of an
2 insoluble material, a soluble material, and a swellable material.

1 51. The process of claim 50, wherein the core comprises an insoluble material.

1 52. The process of claim 51, wherein insoluble material comprises one or more of
2 sand, glass, microcrystalline cellulose, and a plastic material.

1 53. The process of claim 50, wherein the core comprises a soluble material.

1 54. The process of claim 53, wherein the soluble material comprises a sugar
2 comprising one or more of glucose, mannitol, lactose, xylitol, dextrose, and sucrose.

1 55. The process of claim 50, wherein the core comprises a swellable material.

1 56. The process of claim 55, wherein swellable material comprises hydroxypropyl
2 methylcellulose.

1 57. The process of claim 41, wherein the drug comprises one or more of alkaloids,
2 antacids, analgesics, anabolic agents, anti-anginal drugs, anti-allergy agents, anti-
3 arrhythmia agents, antiasthmatics, antibiotics, anticholesterolemics, anticonvulsants,
4 anticoagulants, antidepressants, antidiarrheal preparations, anti-emetics, antihistamines,
5 antihypertensives, anti-infectives, anti-inflammatories, antilipid agents, antimanics, anti-
6 migraine agents, antinauseants, antipsychotics, antistroke agents, antithyroid preparations,
7 anabolic drugs, antiobesity agents, antiparasitics, antipsychotics, antipyretics,
8 antispasmodics, antithrombotics, antitumor agents, antitussives, antiulcer agents, anti-
9 uricemic agents, anxiolytic agents, appetite stimulants, appetite suppressants, beta-
10 blocking agents, bronchodilators, cardiovascular agents, cerebral dilators, chelating agents,
11 cholecystekinin antagonists, chemotherapeutic agents, cholesterol reducing agents,

12 cognition activators, contraceptives, coronary dilators, cough suppressants, CNS drugs,
13 decongestants, diabetes agents, diuretics, emollients, enzymes, erythropoietic drugs,
14 expectorants, fertility agents, fungicides, gastrointestinal agents, growth regulators,
15 hormone replacement agents, hyperglycemic agents, hypoglycemic agents, ion-exchange
16 resins, laxatives, migraine treatments, mineral supplements, mucolytics, narcotics,
17 neuroleptics, neuromuscular drugs, non-steroidal anti-inflammatories (NSAIDs),
18 nutritional additives, peripheral vasodilators, polypeptides, prostaglandins, psychotropics,
19 renin inhibitors, respiratory stimulants, sedatives, steroids, stimulants, sympatholytics,
20 thyroid preparations, tranquilizers, uterine relaxants, vaginal preparations,
21 vasoconstrictors, vasodilators, vertigo agents, vitamins, wound healing agents, and others.

1 58. The process of claim 41, further comprising formulating the taste-masked
2 pharmaceutical composition as sprinkles, a dry powder, a suspension, an emulsion, whole
3 chewable tablets, or dispersible tablets.

1 59. The process of claim 41, wherein the taste-masking coating composition is
2 applied to the drug.

1 60. The process of claim 41, wherein the taste masking coating composition further
2 comprises one or more of a plasticizer, a coloring agent, and a gloss producer.

1 61. A process for preparing a taste-masked pharmaceutical composition, the
2 process comprising:

3 coating one or more microcrystalline cellulose beads with a suspension containing
4 at least one active pharmaceutical ingredient to form one or more drug loaded beads;

5 coating the drug loaded beads with a taste masking coating composition
6 comprising (i) 25% w/w of the total taste masking coating composition of a copolymer of
7 acrylate and methacrylate with a quaternary ammonium group in combination with sodium
8 carboxymethylcellulose and (ii) 68.5% w/w of the total taste masking coating composition
9 of polyvinyl alcohol-polyethylene glycol copolymer.

1 62. A method of treating, preventing or diagnosing a disease condition by orally
2 administering a taste-masked pharmaceutical composition to a patient in need thereof, the
3 pharmaceutical composition comprising a core containing an active pharmaceutical
4 ingredient and a taste masking coating composition, the taste masking coating composition
5 forming a coat around at least a portion of the core and comprising a combination of (i) a
6 copolymer of acrylate and methacrylate with a quaternary ammonium group in

- 7 combination with sodium carboxymethylcellulose and (ii) a polyvinyl alcohol-
- 8 polyethylene glycol copolymer.